Serial No. 10/789,398
Examiner Thomas Sweet

STATUS OF CLAIMS

Claims 1-94 are pending in the application. Claims 1-72 were withdrawn pursuant to an election requirement. Applicants hereby amend claims 73 and 75. Applicants have added new dependent claims 95-104. Support for the amendment to claim 73 is provided in the original claims and specification as filed, and specifically, in paragraphs [0011], [0042]. Support for the amendment to claim 75 is provided, for example, in paragraph [0011] of the specification. Support for new dependent claims 95-104 is provided in the original claims and specification as filed, and specifically, in paragraphs [0010], [0039], [0040], [0041], [0044], [0047], [0050], [0062], of the specification and original claims 1, 8, 10, 13, 15, 20, 21, 34, 39, 69, 72, 80 82, and 83. Applicants state that there is no issue of new matter.

REMARKS

Provisional non-statutory double patenting rejection

Claims 73-74, 76-77, 80-82, 84, and 86 are provisionally rejected on the grounds of non-statutory obviousness-type double patenting as being unpatentable over claims 22, 24, 25, 27, 30-33 of co-pending Application No. 11/125,296. Claims 73-74, 76-77 and 84 are provisionally rejected on the grounds of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 8, 9, and 14 of co-pending Application No. 11/188,367.

In response, Applicants respectfully traverse the non-statutory obviousness-type double patenting rejection and its accompanying remarks. Applicants also respectfully state that the instant double patenting rejections will be addressed if and when the "provisional" non-statutory obviousness-type double patenting rejection in each application is the only rejection remaining in that application. Pursuant to MPEP 804 I B,

> *If the "provisional" double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection* and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent.

Thus, since the co-pending applications have not issued as patents and the claims may be amended in the future, Applicants respectfully exercise their right to address the provisional rejections at a future date, if and when the cited applications are issued as patents.

Rejection Under 35 U.S.C. § 102(a)/(e) and 103(a) – Schwarz et al.

Claims 73-74, 76-77, 80, and 82 are rejected under 35 U.S.C. § 102(a)/(e) as being anticipated by Schwarz et al. (U.S. Pub. No. 2001/0022988). Specifically, the Examiner states that Schwarz et al. discloses a stent comprising a polymeric tubular shaft, said polymeric subular shaft comprising triclosan and a matrix polymer. In addition, Claim 84 was rejected under 35 U.S.C. 102(a) or in the alternative, under 35 U.S.C. 103(a) as obvious over Schwarz et al.

In response, Applicants respectfully traverse the rejections and their accompanying remarks. Schwarz et al. does not teach the invention of the claims. Specifically, Schwarz et al. fails to teach all of the elements of the present invention as claimed in amended independent claim 73, which is directed to a stent comprising a polymeric tubular shaft, said polymeric tubular shaft comprising *a matrix polymer comprising an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor* (emphasis added).

For a reference to anticipate a claim it must disclose ***each and every element*** of the claim. *See* MPEP 2131 and cases cited therein, *especially Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (Fed. Cir. 1978)(emphasis added).

The Schwarz et al. reference fails as an anticipatory reference because it fails to disclose all of the features of the claimed invention. For example, Schwarz et al. fails to teach a microbial attachment/biofilm synthesis inhibitor. Schwarz et al. fails to teach a matrix polymer having both the inhibitor and an antimicrobial agent.

As explained by Applicants in paragraphs [003] to [0010] of the specification, prior art devices with antimicrobial coatings have failed to provide adequate resistance to microbial growth since "[a]ntimicrobial agents have difficulty penetrating biofilms and killing and/or inhibiting the proliferation of the microorganisms within the biofilm."

Applicants have solved this problem by providing a stent device having *both* an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor.

In contrast, Schwarz et al. does not teach the invention of the claims and specifically, Schwarz et al. does not teach or suggest the use of a separate microbial attachment/biofilm synthesis inhibitor in addition to an antimicrobial agent.

Regarding coatings, Schwarz et al. provides little guidance, stating merely that "[t]he coating materials used in conjunction with the present invention are *any desired, suitable substances*. In some embodiments, the coating materials comprise therapeutic agents." (Schwarz et al., paragraph [0027])(emphasis added). The antimicrobial agent, triclosan, appears in a long list of exemplary therapeutic agents for use in conjunction with coatings produced from the disclosed coating process. (paragraph [0028]). Schwarz et al. fails to provide an enabling disclosure for the specific composition of the claimed device, wherein a polymeric tubular shaft comprises both an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor. This lack of guidance is not surprising since the focus of Schwarz et al. is not on coating compositions. Rather, Schwarz et al. teaches a method for coating medical devices using air suspension techniques and coated articles made according to this method (*see* paragraphs [007], [0035] to [0037]). Schwarz et al. also teaches an open-structure cage for protecting a medical device during a coating process (*see* Figures 4 and 5 and accompanying text).

Applicants respectfully state that Schwarz et al. fails to teach, either inherently or explicitly, the claimed stent wherein said polymeric tubular shaft comprises an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor. Since Schwarz et al. is missing a disclosure of all of the claimed elements, fails to anticipate the invention as claimed. Claim 73 is an independent claim, and the above comments apply directly to it. All other rejected claims are dependent directly on claim 73 and the rejection of those claims fails at least because of the fundamental defect discussed above. Thus, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection under § 102(a)/(e) as anticipated by Schwarz et al.

Further, Applicant states that claim 84 is not obvious over Schwarz et al. Applicant states that the Examiner has not met his burden of establishing a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, three basic criteria

must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claimed features. In addition, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The rejection fails at least because of the fundamental defects discussed above with respect to the rejection of the claims as being anticipated by Schwarz et al. The Schwarz et al. reference fails to teach or suggest all the claimed features. In addition, claim 84 provides other additional distinguishing features not taught in Schwarz et al. As such, Applicant respectfully submits that claim 84 is patentable over the cited references and requests that the Examiner reconsider and withdraw the rejection of claim 84 over Schwarz et al.

Rejection Under 35 U.S.C. § 102(e) – Pinchuk et al.

Claims 73-74, 76-77 and 84 are rejected under 35 U.S.C. § 102(e) as being anticipated by Pinchuk et al. (U.S. Pub. No. 2002/0107330). Specifically, the Examiner states that Pinchuk et al. discloses a stent comprising a polymeric tubular shaft comprising triclosan and a matrix polymer.

In response, Applicants respectfully traverse the rejection and their accompanying remarks. Pinchuk et al. does not teach the invention of the claims. Pinchuk et al. fails to teach all of the elements of the present invention as claimed in independent claim 73, which is directed to a stent comprising a polymeric tubular shaft, said polymeric tubular shaft comprising *a matrix polymer comprising an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor* (emphasis added).

The Pinchuk et al. reference fails as an anticipatory reference because it fails to teach a required element, e.g., a "microbial attachment/biofilm synthesis inhibitor." As stated above, for a reference to anticipate a claim it must disclose each and every element of the claim. *See* MPEP 2131 and cases cited therein, *especially Richardson v. Suzuki*

Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (Fed. Cir. 1978).

Pinchuk et al. teaches block copolymer compositions. Specifically, it teaches styrene-isobutylene-styrene block copolymers with an optional supplemental polymer such as ethylene-vinyl acetate copolymer (paragraph [0016]). The antimicrobial agent, triclosan, appears in a list of hundreds of exemplary therapeutic agents that can be used with the disclosed block copolymers "to provide therapeutic-agent-loaded block copolymer compositions for therapeutic agent delivery." (paragraphs [0059] and [0060] to [0175]).

Pinchuk et al. fails to provide an enabling disclosure for the specific composition of the claimed device, wherein a polymeric tubular shaft comprises both an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor. There is no teaching or suggestion of the problem of biofilm formation in stents or the disclosure of compositions to solve this problem. Pinchuk et al. fails to explicitly or inherently teach a microbial attachment/biofilm synthesis inhibitor. Pinchuk et al. fails to explicitly or inherently teach the combination of both an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor in the device. As such, Pinchuk et al. fails as an anticipatory reference. Claim 73 is an independent claim, and the above comments apply directly to it. All other rejected claims are dependent directly on claim 73 and the rejection of those claims fails at least because of the fundamental defect discussed above. Thus, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection under § 102(e) as anticipated by Pinchuk et al.

Rejection Under 35 U.S.C. § 102(e) – Bucay-Couto et al.

Claims 73-74, 76-77 and 84 are rejected under 35 U.S.C. § 102(e) as being anticipated by Bucay-Couto et al. (U.S. Pub. No. 2003/0018306). Specifically, the Examiner state that Bucay-Couto et al. discloses a stent comprising a polymeric tubular shaft, said polymeric tubular shaft comprising triclosan and a matrix polymer.
Claims 73-74, 76-77 and 84 are rejected under 35 U.S.C. § 102(e) as being anticipated by Pinchuk et al. (U.S. Pub. No. 2002/0107330). Specifically, the Examiner states that

Pinchuk et al. discloses a stent comprising a polymeric tubular shaft comprising triclosan and a matrix polymer.

In response, Applicants respectfully traverse the rejection and their accompanying remarks. Bucay-Couto et al. does not teach the invention of the claims. Bucay-Couto et al. fails to teach all of the elements of the present invention as claimed in independent claim 73, which is directed to a stent comprising a polymeric tubular shaft, said polymeric tubular shaft comprising *a matrix polymer comprising an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor* (emphasis added).

The Bucay-Couto et al. reference fails as an anticipatory reference because it fails to teach a required element, e.g., *a matrix polymer comprising an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor.* Rather, Bucay-Couto et al. discloses "a medical device 20 [which] includes a polymer matrix portion 22, within which is disposed one or more broad-spectrum antimicrobial agents, the polymer matrix portion 22 acts as a slow-release reservoir, or depot, for the antimicrobial agents. *A surfactant region 24 is disposed over the polymer matrix portion* 22 at the surface of the device 20." (Bucay-Couto et al., paragraph [0023])(emphasis added).

Thus, Bucay-Couto et al. teaches a device having structure that is distinct from that of the present invention. Instead of Applicants' claimed matrix polymer comprising an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor, Bucay-Couto et al. teaches a separate surface region 24 made of "biosurfactants" (defined as "agents produced by microorganisms and other biological sources (e.g., plants) that bring about a reduction in the surface tension of liquids, most notably aqueous-based liquids")(paragraph [0038]) or "surfactant polymer" (defined as "polymers having both hydrophobic and hydrophilic groups that bring about a reduction in the surface tension of liquids, most notably aqueous-based liquids)" (paragraphs [0036] to [0037]). Thus, even assuming for the sake of argument that the surfactant region 24 of Bucay-Couto et al. reads on the claimed "microbial attachment/biofilm synthesis inhibitor," which it does not, Bucay-Couto et al. fails as an anticipatory reference since it does not disclose a matrix portion comprising an antimicrobial agent and a microbial attachment/biofilm synthesis inhibitor. Rather, Bucay-Bouto et al. states repeatedly that the surfactant region 24 is *separate* from the polymer matrix portion 22, i.e., surfactant region 24 is *disposed*

over the polymer matrix portion 22 at the surface of the device 20 (*see* Bucay-Couto et al., paragraphs [0005], [0013], [0023], [0041] and [0042]).

As such, Bucay-Couto et al. fails as an anticipatory reference. Claim 73 is an independent claim, and the above comments apply directly to it. All other rejected claims are dependent directly on claim 73 and the rejection of those claims fails at least because of the fundamental defect discussed above. Thus, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection under § 102(e) as anticipated by Bucay-Couto et al.

Rejection Under 35 U.S.C. 103(a) – Pinchuk et al.

Claims 75, 78-83, and 85-94 are rejected under 35 U.S.C. 103(a) as being obvious over Pinchuk et al. (U.S. Pub. No. 20020107330).

In response, Applicants respectfully traverse the rejections and their supporting remarks. Applicants state that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a) via 35 U.S.C. 102(e). As stated by the Examiner, Pinchuk et al. constitutes prior art only under 35 U.S.C. 102(e).

Applicants state that the subject matter of the claimed invention was, at the time the claimed invention was made, owned by the same entity or subject to an obligation of assignment to the same entity, i.e. Boston Scientific SciMed, Inc. Thus, Applicants state Pinchuk et al. is disqualified as prior in accordance with 35 U.S.C. 103(a) and the rejection under 103(a) has been overcome.

In addition, Applicants state that the Examiner has not met his burden of establishing a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claimed features. In addition, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicants state that the rejection fails at least because of the fundamental defects discussed above regarding the rejection under 35 U.S.C. § 102(e) over Pinchuk et al. As indicated above with respect to the anticipatory rejection over Pinchuk et al., Pinchuk et al. fails to teach all of the claimed features of the independent claims and also the dependent claims which contain additional distinguishing features.

For at least these reasons, Applicants respectfully submit that the rejection under 35 U.S.C. § 103(a) over Pinchuk et al. has been overcome.

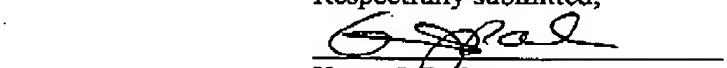
CONCLUSION

Given the above remarks and amendments to the claims, Applicants state that the Examiner's rejections under 35 U.S.C § 102(a)/(e) and § 103(a) have been obviated and Applicants respectfully requests that the Examiner withdraw the rejections. Applicants respectfully submit that all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite the application at large, request is made that the Examiner telephone the undersigned attorney at (908) 518-7700, ext. 7 in order to resolve any outstanding issues.

FEES

The Office is authorized to charge any fees required to deposit account number 50-1047.

Respectfully submitted,



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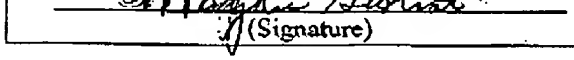

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